IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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o In re the application of: Acton, et al.

rial No.: 09/779,152

iled: February 8, 2001

For: Diagnostic Assays and Kits for Body Mass and

Cardiovascular Disorders

Attorney Docket No.: MNI-172CP2

Commissioner for Patents Washington, D.C. 20231

Group Art Unit: 1655

Examiner: Chakrabarti, A.

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January 11, 2002

Date of Signature and of Mail Deposit

By:

DeAnn F. Smith, Esq. Attorney for Applicants

Reg. No. 36,683

PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action dated December 12, 2001 (Paper No. 7). Prior to examination, please amend the application as follows:

In the claims:

Please cancel claims 23-33 and amend claims 3, 20, 22, and 34 as follows:

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3. A method of claim 2, wherein the exon is exon 8.

20. A method of claim 1, wherein determining the identity of the allelic variant of a polymorphic region is carried out by single-stranded conformation polymorphism.

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22. A method of claim 21, comprising determining the identity of the nucleotide at position 41 in exon 8 and/or nucleotide 54 in intron 5, wherein the presence of a cytidine at position 41 of exon 8 and/or the presence of a thymidine at position 54 of intron 5 indicates that the subject has or is at risk of developing an abnormally low HDL level.

34. A method for predicting the effect of hormone replacement therapy on the HDL level in a female subject comprising identifying one or more allelic variants of the SR-B1 gene which are associated with abnormally low HDL levels in females, thereby predicting the effect of hormone replacement therapy on the HDL level in the subject.

REMARKS

Claims 1-38 were pending in the present application. Claims 23-33 have been cancelled without prejudice and claims 3, 20, 22, and 34 have been amended. Accordingly, claims 1-22 and 34-38 will be pending in the instant application after the amendments presented herein have been entered. Applicants respectfully submit that claims 1-22 and 34-38 are directed to the elected invention. For the Examiner's convenience, the pending claims are set forth in Appendix A.

Support for amendments to claims 3, 20, 22, and 34 can be found throughout the specification, including the claims as originally filed.

Applicants submit herewith a "Version with Markings to Show Changes Made," which indicates the specific amendments made to the specification and the claims. *No new matter has been added.*

Any amendments to and/or cancellation of the claims was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Election/Restriction

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- I. Claims 1-22 and 34-38, drawn to method of determining disease and prediction of hormone therapy by nucleic acid hybridization, classified in class 435, subclass 6.
- II. Claims 23-33, drawn to kit containing nucleic acids, classified in class 536, subclass 22.1+.

Applicants hereby elect the <u>Group I</u> invention (claims 1-22 and 34-38) for prosecution in this application, *without traverse*.

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SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,

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Dated: January 11, 2002